UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION	No. 15-cv-7488-CM

DIRECT PURCHASER CLASS PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT ON COUNT THREE

FILED UNDER SEAL

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

I. INTRODUCTION

Defendant Forest[1] entered into agreements to settle patent litigation with multiple generic drug companies (the "Challenged Agreements") that had asserted that their respective generic versions of Namenda IR did not infringe Forest's U.S. Patent No. 5,061,703 (the "'703 patent" or the "patent") and that the '703 patent was invalid and unenforceable. The Challenged Agreements each contained the following provision (the "Pediatric Extension Provision") that is the subject of this motion:

> **"Launch Date"** shall mean the later of: (a) 3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Execution Date; or (b) the date that [the settling generic company] obtains final approval from the FDA of the [settling generic company's] ANDA, unless accelerated as described [herein].

See Statement of Material Facts of Direct Purchaser Plaintiffs in Support of Their Motion for Partial Summary Judgment ("SMF") ¶¶ 26 (Amneal), 40 (Dr. Reddy's), 54 (Lupin), 68 (Mylan), 82 (Orchid), 95 (Sun), 109 (Teva). In application, this provision prevented the generic drug companies from entering the market until three (3) months *after* expiration of the '703 patent.

The Pediatric Extension Provision is contrary to patent law in that it provides a patent license beyond the term of the patent. This is contrary to the Supreme Court's decisions in *Brulotte v. Thys Co.*, 379 U.S. 29, 31 (1964) and *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2407 (2015). The Pediatric Extension Provision is also contrary to the antitrust laws because, there being no legal basis for two competitors to agree not to compete – particularly after expiration of the '703 patent – it constitutes a naked market allocation agreement that is *per se*

[1] "Forest" refers to defendant refers to Forest Laboratories, LLC. "Defendants" refers to Forest, Actavis, PLC, Merz GMBH & Co. KGAA, Merz Pharma GMBH & Co. KGAA, and Merz Pharmaceuticals GMBH (collectively "Merz").

illegal under the Supreme Court's decision in *United States v. Topco Assocs.*, 405 U.S. 596, 600-601, 607-610 (1972) and its progeny.

Pursuant to the Pediatric Extension Provision, seven generic companies[2] agreed not to compete with Forest for a period of three months after expiration of the '703 patent despite the fact that these generic companies (hereinafter the "7 Generic Companies") had FDA final approval by the time the '703 patent expired and – other than as a result of this illegal contractual provision – were not restricted in any way from launching upon expiration of that patent. It is on this narrow ground alone that Plaintiffs[3] seek summary judgment declaring the Pediatric Extension Provision, as entered into between Forest and the 7 Generic Companies in the Challenged Agreements, to be a naked restraint of trade and, hence, a *per se* violation of Section 1 of the Sherman Act.[4]

Specifically, the Pediatric Extension Provision constitutes a naked restraint of trade for the following reasons:

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[2] The seven generic companies were: Interpharm Holdings, Inc. and Interpharm, Inc. (together, "Interpharm") (whose interests were acquired by a wholly owned subsidiary of Amneal Pharmaceuticals, LLC ("Amneal")); Dr. Reddy's Laboratories Ltd. and/or Dr. Reddy's Laboratories, Inc. (together, "Dr. Reddy's"); Lupin Pharmaceuticals, Inc. ("Lupin"); Mylan Pharmaceuticals, Inc. ("Mylan"); Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid"); Sun India Pharmaceuticals Industries, Lted. ("Sun"); and Teva Pharmaceuticals USA, Inc. ("Teva").

[3] "Plaintiffs" refers to the Direct Purchaser Class Plaintiffs, including J M Smith Corp., d/b/a Smith Drug Company; Rochester Drug Co-Operative, Inc.; and the putative class in this matter.

[4] By this motion, Plaintiffs seek partial summary judgment only with respect to the violation. Plaintiffs, at this point, are not seeking summary judgment with respect to causation or damages. In further proceedings, Plaintiffs will establish that, but for the illegal Pediatric Extension Provision, the parties settling patent litigation over the '703 patent, including Forest, would have provided for an entry date of January 11, 2015 (three months prior to the '703 patent expiry) and that numerous companies would have launched generic versions of Namenda IR by that date.

1. In application, the Pediatric Extension Provision mandated that the 7 Generic Companies could not launch their respective generic versions of Namenda IR until three months after expiration of the '703 patent because Forest had obtained a six-month pediatric exclusivity period from the FDA.

2. But, as a matter of clear and unambiguous regulatory law, the six-month pediatric exclusivity period was *not* a barrier to the 7 Generic Companies' market entry for the three months mandated under the Pediatric Extension Provision after expiration of the '703 patent because the 7 Generic Companies (a) filed, and then maintained throughout the entire time period at issue, abbreviated new drug applications (each, an "ANDA") with the FDA that included certifications that their respective generic products either did not infringe that patent or that the patent was unenforceable or invalid (each, a "Paragraph IV certification") and (b) had received FDA final approval prior to expiration of the '703 patent. This is indisputably evidenced by the 7 Generic Companies' receipt of FDA final approval to sell and market their generic Namenda IR products prior to expiration of the '703 patent, and the 7 Generic Companies' maintenance of those final approvals notwithstanding Forest's receipt of the pediatric exclusivity period.

3. The Pediatric Extension Provision was in no way, shape or form a patent license under 35 U.S.C. § 261 of the Patent Act in that (a) "[a] pediatric exclusivity period is not an extension of the term of the patent," *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1343 (Fed Cir. 2015); (b) "any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws," *Brulotte*, 379 U.S. at 31; *see also Kimble*, 135 S. Ct. 2401, 2407;[5] and (c) nevertheless, and as stated above, pursuant to clear regulatory law, Forest's receipt of the six-month pediatric exclusivity was not a barrier to the 7 Generic Companies' market entry after they received FDA final approval, even after settling with Forest.[6]

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[5] The Department of Justice has supported Plaintiffs' analysis in this regard in an Amicus Brief to the U.S. Supreme Court. Brief for the United States as Amicus Curiae, at 12-15, *SmithKline Beecham Corp. v. King Drug Co.*, 137 S. Ct. 446, 2016 WL 5765167 (U.S. Oct. 3, 2016) (No. 15-1055), *cert. denied*, (Nov. 7, 2016) (available at https://www.justice.gov/atr/file/900991/download).

[6] The fact that the 7 Generic Companies maintained their Paragraph IV certifications to the '703 patent was not by accident or oversight. It was only through this maintenance that Forest and the 7 Generic Companies guaranteed that the six-month pediatric exclusivity period would not be a barrier to their entry after expiration of the '703 patent but prior to the six-month period

4. The pediatric exclusivity statute, which reads as follows, is clear and unambiguous:

> [I]f the [brand] drug is the subject of a listed patent for which a [Paragraph IV] certification has been submitted…and in the patent infringement litigation resulting from the [Paragraph IV] certification the court determines that the patent is valid and would be infringed, the period during which an [ANDA] may not be approved…shall be extended by a period of six months after the date the patent expires.

21 U.S.C. § 355a(c)(1)(B)(ii). In order for pediatric exclusivity to affirmatively prevent FDA final approval and market entry of a generic competitor that had filed and maintained a Paragraph IV certification prior to the expiration of the '703 patent, Forest would have had to obtain a "court determin[ation] that the patent is valid and would be infringed." 21 U.S.C. § 355a(c)(1)(B)(ii). Not only did Forest never obtain such a court determination, Defendants, by settling with multiple generic drug manufacturers (including the 7 Generic Companies) intentionally prevented a court from ever being able to make any determination of the sort.

Because the Pediatric Extension Provision in the Challenged Agreements clearly restricts competition for a period of time during which none of the 7 Generic Companies was precluded in any way, or for any reason, from selling its generic version of Namenda IR on the market pursuant to any patent or regulatory exclusivity, the Pediatric Extension Provision can only be viewed as a naked restraint of trade that is condemned as a *per se* violation of the Sherman Act.

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thereafter. Furthermore, Forest's agreements with each of the 7 Generic Companies contained a contingent launch provision that allowed any of the seven to come to market even earlier should any other generic company do so. SMF ¶¶ 25 (Amneal), 39 (Dr. Reddy's), 53 (Lupin), 67 (Mylan), 81 (Orchid), 94 (Sun), 108 (Teva). The only way to effectuate this term and possibility was through maintenance of the Paragraph IV certifications because, if the 7 Generic Companies were to change their certifications from Paragraph IV to Paragraph III – which would mean they do not seek to market their generic products until after the patent expires – then the 7 Generic Companies would be subjected to Forest's pediatric exclusivity and would be unable to obtain or maintain FDA final approval until after Forest's pediatric exclusivity expired.

See, e.g., *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 48-50 (1990) (per curiam); *United States v. Topco Assocs.*, 405 U.S. 596, 600-601, 607-610 (1972).

II. FACTUAL AND REGULATORY BACKGROUND

A. Forest's Namenda Product.

Forest, now Allergan, markets memantine hydrochloride in the United States as "Namenda". SMF ¶ 1. The FDA has approved Namenda for use in patients with moderate and severe Alzheimer's disease. SMF ¶ 2.

On or about June 2000, Forest and Merz, a German company, entered into a license and cooperation agreement for the development of memantine hydrochloride to be used for Alzheimer's disease. SMF ¶ 3. As part of that agreement, Forest obtained exclusive rights to market a memantine hydrochloride product in the United States under Merz's '703 patent. SMF ¶ 4.

In December 2002, Forest submitted New Drug Application No. 21-487 to the FDA, seeking approval to market memantine hydrochloride tablets (5mg and 10mg) — branded as Namenda — for the treatment of Alzheimer's.[7] SMF ¶ 5. Forest's NDA was approved in October 2003 for Namenda immediate release (IR) tablets. SMF ¶ 6. In January 2004, Forest commercially launched Namenda IR tablets in the United States. SMF ¶ 7.

[7] Under the Federal Food, Drug, and Cosmetic Act, manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

In conjunction with obtaining regulatory approval of Nameda, the '703 patent was listed in the FDA's "Orange Book" as covering Namenda.[8] SMF ¶ 8. The '703 patent, which was obtained in 1991, originally expired on April 11, 2010. SMF ¶ 9. Forest submitted an application to the Patent and Trademark Office (the "PTO") seeking a five-year patent extension (the maximum allowed under the Hatch-Waxman Act) to account for the time Forest spent obtaining FDA approval for Namenda IR tablets (during which time the patent "clock" was ticking but Forest could not market the drug). SMF ¶ 10. In March 2009, the PTO granted Forest the five-year extension. SMF ¶ 11. As a result, the term of the '703 patent was extended, from its original expiration date, to April 11, 2015. SMF ¶ 12.

In January 2014, Forest sought six months of pediatric exclusivity for Namenda IR tablets from FDA.[9] SMF ¶ 13. This request was based on studies regarding the use of memantine hydrochloride in pediatric patients with autism. SMF ¶ 14. In June 2014, FDA granted Forest's request for six months of pediatric exclusivity. SMF ¶ 15. As a result, the earliest date that the

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[8] When the FDA approves a brand manufacturer's NDA, the manufacturer must list in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book"), any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. 21 U.S.C. §§ 355(b)(1).

[9] In addition to patent protection, a brand manufacturer may obtain periods of regulatory exclusivities. For example, "pediatric exclusivity" is a form of regulatory exclusivity, wholly unrelated to patents, created to encourage studies on the use of brand drugs in children. If a brand manufacturer completes pediatric studies on one of its drugs, after being asked to do so by the FDA, and the FDA accepts the results, then the FDA generally may not approve an application for that same drug until six months after the expiration of the then-existing brand manufacturer's patent or regulatory exclusivities. 21 U.S.C. § 355a(c)(1). However, pediatric exclusivity neither prohibits the FDA from granting final approval to a generic applicant that files and maintains a Paragraph IV certification nor prevents a generic company with FDA final approval prior to the expiration of that patent from entering the market with its generic product if there is no "court determin[ation] that the patent is valid and would be infringed." 21 U.S.C. § 355a(c)(1)(B)(II).

FDA would grant final approval and therefore permit a generic manufacturer *that did not wish to challenge the'703 patent* to come to market with an AB-rated equivalent of Namenda IR was October 11, 2015.[10] However, the 7 Generic Companies obtained FDA final approval after filing and maintaining Paragraph IV certifications to the '703 patent so that, under the pediatric exclusivity statute, 21 U.S.C. § 355a(c)(1)(B)(ii), the only way that Forest's receipt of pediatric exclusivity could bar their market entry, after expiration of that patent, was if Forest obtained a judicial ruling of validity and infringement. *See* SMF ¶ 16.

B. Generic Namenda Competitors and Defendants' Lawsuits Filed Against Them

In late 2007, the 7 Generic Companies filed ANDAs with the FDA seeking to market AB-rated generic formulations of Namenda IR.[11] SMF ¶¶ 17 (Amneal), 31 (Dr. Reddy's), 45 (Lupin), 59 (Mylan), 73 (Orchid), 86 (Sun), 100 (Teva). The 7 Generic Companies' ANDAs included Paragraph IV certifications that stated that the '703 patent was invalid and/or not

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[10] This date is 6 months after the expiration of the '703 patent on April 11, 2015. *See* 21 U.S.C. § 355a(c)(1)(B)(II).

[11] The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for generic manufacturers to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Instead, a generic manufacturer seeking approval to sell a generic version of a brand drug may file an Abbreviated New Drug Application ("ANDA"). A generic manufacturer's ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA. A generic manufacturer's ANDA must demonstrate that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug. It must also show that the generic drug is absorbed in the blood at the same rate, and to the same extent, as the brand drug. Such a showing establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns an "AB rating" to generic drugs that are therapeutically equivalent to, and are of the same dosage strength and form as, their brand counterpart. An "AB rating" means the FDA has determined that the generic drug can be substituted for the brand drug at the pharmacy with the full expectation that the generic drug will produce the same clinical effect and safety profile as the brand drug. *Preface* to Orange Book at vii (37th ed. 2017).

infringed by their products.[12] SMF ¶¶ 20 (Amneal), 34 (Dr. Reddy's), 48 (Lupin), 62 (Mylan), 76 (Orchid), 89 (Sun), 103 (Teva). Forest received notice of Paragraph IV certifications from the 7 Generic Companies on various dates from late November 2007 through early January 2008.[13]

In January 2008, Forest and Merz filed Hatch-Waxman lawsuits in the United States District Court for the District of Delaware against the 7 Generic Companies alleging infringement of the '703 patent.[14] Merely by filing these suits (and regardless of their merit or lack thereof), Forest and Merz triggered automatic stays to the ability of FDA to approve these ANDAs through April 16, 2011.[15] This date was 7.5 years from the date that Forest's Namenda

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[12] To obtain FDA approval of an ANDA, a generic manufacturer may make a certification to any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA may contain one of four certifications: (i) that no patent for the brand drug has been filed with the FDA; (ii) that the patent for the brand drug has expired; (iii) that the manufacturer does not seek to market its generic product before the patent for the brand drug expires; or (iv) that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product. 21 U.S.C. § 355(j)(2)(A)(vii).

[13] Specifically, Teva sent its Paragraph IV notice to Forest on November 30, 2007. SMF ¶ 102. Orchid sent its Paragraph IV notice on December 11, 2007. SMF ¶ 75. Lupin sent its Paragraph IV notice on December 14, 2007. SMF ¶ 47. Mylan sent its Paragraph IV notice on December 18, 2007. SMF ¶ 61. Interpharm (now Amneal) sent its Paragraph IV notice on December 19, 2007. SMF ¶ 19. Sun sent its Paragraph IV notice on December 20, 2007. SMF ¶ 88. And Dr. Reddy's sent its Paragraph IV notice on January 4, 2008. SMF ¶ 33.

[14] Forest and Merz filed an initial suit against Lupin, Orchid, and Teva on January 10, 2008 and then filed a second suit against Dr. Reddy's, Interpharm (for whom Amneal was later substituted), Mylan and Sun on January 25, 2008. *See* SMF, at ¶¶ 21 (Amneal), 35 (Dr. Reddy's), 49 (Lupin), 63 (Mylan), 77 (Orchid), 90 (Sun), 104 (Teva). These two suits were consolidated under lead case number 08-cv-00021 (D. Del.) on June 2, 2008. *See* SMF, at ¶¶ 22 (Amneal), 36 (Dr. Reddy's), 50 (Lupin), 64 (Mylan), 78 (Orchid), 91 (Sun), 105 (Teva).

[15] If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement within forty-five days of receiving notification of the Paragraph IV certification. If the brand manufacturer initiates such a patent infringement action against the generic filer, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months from the date of receipt of the Paragraph IV

NDA was originally approved.[16] During this 7.5 year period, the FDA was not permitted to approve any of the aforementioned generic manufacturers' ANDAs for AB-rated equivalents to Namenda tablets.[17]

C. Defendants' Settlements With the 7 Generic Companies

Forest and Merz settled with the 7 Generic Companies on or about the following dates: Amneal (September 2009); Sun (October 2009); Lupin (December 2009); Teva (November 2009); Dr. Reddy's (November 2009); Orchid (April 2010); and Mylan (July 2010). SMF ¶¶ 23 (Amneal), 37 (Dr. Reddy's), 51 (Lupin), 65 (Mylan), 79 (Orchid), 92 (Sun), 106 (Teva).

In connection with these settlements, the 7 Generic Companies agreed, among other things, to (1) discontinue their efforts to challenge the '703 patent and (2) not launch their

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notice (the "30-month stay") or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). The aforementioned 30-month stay of FDA marketing approval may be extended under specified circumstances. The Hatch-Waxman Act provides for a five-year marketing exclusivity period for a brand drug with an active ingredient that qualifies as a new chemical entity ("NCE"). During this five-year period, a generic manufacturer may not file an ANDA for a drug that seeks an AB-rating to a particular brand drug that has NCE exclusivity. However, ANDA applications that include a Paragraph IV certification may be filed after the fourth year of the five-year NCE exclusivity period. 21 U.S.C. § 355(j)(5)(F)(ii). In the event that a Paragraph IV ANDA application is filed after the end of that fourth year, but before the end of the fifth year, and a lawsuit is commenced within forty-five days of the receipt of the Paragraph IV certification notice, the Hatch-Waxman Act requires that the 30-month stay be "extended by such amount of time (if any) which is required for [7.5] years to have elapsed from the date of approval" of the NDA. 21 U.S.C. § 355(j)(5)(F) (ii). This 7.5 year period may be extended by six months, to 8 years, if the brand manufacturer obtains pediatric exclusivity prior to the end of the 7.5 year period. *See* 21 U.S.C. § 355a(b)(1) (A)(i)-(ii), (c)(1)(A)(i)-(ii). Because Forest sued the 7 Generic Companies within 45 days of receiving notices of Paragraph IV certifications during year 4 of the 5-year NCE period, the FDA was stayed from approving the 7 Generic Companies' applications until April 16, 2011, *i.e.*, 7.5 years from the date Forest received approval for Namenda IR on Oct. 16, 2003.

16 *See* note 15, *supra*.

17 *See* note 15, *supra*.

generic products until the exact same day approximately five years later. SMF ¶¶ 24-25 (Amneal), 38-39 (Dr. Reddy's), 52-53 (Lupin), 66-67 (Mylan), 80-81 (Orchid), 93-94 (Sun), 107-108 (Teva). Each of these agreements contained the Pediatric Extension Provision that extended the agreed-upon generic launch date from January 11, 2015 (three months prior to patent expiry) to July 11, 2015 (three months after patent expiry) in the event that, subsequent to the consummation of the execution of these agreements, Forest was granted an additional six-month pediatric exclusivity period for Namenda. SMF ¶¶ 26 (Amneal), 40 (Dr. Reddy's), 54 (Lupin), 68 (Mylan), 82 (Orchid), 95 (Sun), 109 (Teva).

The 7 Generic Companies maintained Paragraph IV certifications to the '703 patent despite the settlement of the patent lawsuits with Forest. SMF ¶¶ 27 (Amneal), 41 (Dr. Reddy's), 55 (Lupin), 69 (Mylan), 83 (Orchid), 96 (Sun), 110 (Teva). As a result of their maintenance of their Paragraph IV certifications, Forest's pediatric exclusivity would not, and did not, prevent the 7 Generic Companies from obtaining FDA final approval to market and sell their generic versions of Namenda prior to the April 11, 2015 expiration of the '703 patent.[18]

D. FDA Approval of Generic Namenda

The FDA granted final approval to the 7 Generic Companies on the following dates: Dr. Reddy's on April 14, 2010; Sun on May 5, 2010; Teva on October 25, 2011; Orchid on March 12, 2012; Mylan on January 30, 2015; Amneal on April 10, 2015; and Lupin on April 10, 2015. SMF ¶¶ 28 (Amneal), 42 (Dr. Reddy's), 56 (Lupin), 70 (Mylan), 84 (Orchid), 97 (Sun), 111 (Teva). The FDA never rescinded final approval for the 7 Generic Companies because they

[18] Absent a court finding of validity and infringement on the '703 patent, the 7 Generic Companies were free to obtain FDA final approval and launch as soon as they were otherwise approvable by virtue of their Paragraph IV certifications to the '703 patent. *See* 21 U.S.C. § 355a(c)(1)(B)(ii).

maintained Paragraph IV certifications to the '703 patent notwithstanding Forest's pediatric exclusivity. SMF ¶¶ 29 (Amneal), 43 (Dr. Reddy's), 57 (Lupin), 71 (Mylan), 85 (Orchid), 98 (Sun), 112 (Teva).

Pursuant to the Challenged Agreements, by July 11, 2015, at least five of the Generic Companies, including Dr. Reddy's, Sun, Mylan, Amneal, and Lupin, began commercially marketing their versions of immediate release Namenda tablets in the U.S. (three months after the '703 patent expired) in accordance with the challenged Pediatric Extension Provision. SMF ¶¶ 30 (Amneal), 44 (Dr. Reddy's), 58 (Lupin), 72 (Mylan), 107 (Sun).

III. ARGUMENT

A. The Undisputed Facts Establish That The Challenged Agreements Are *Per Se* Anticompetitive Because They Delayed Generic Competition Beyond the Expiration of the '703 Patent.

In *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), the Supreme Court held that "any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws." *Brulotte*, 379 U.S. at 31 (quoting *Scott Paper Co. v. Marcalus Co.*, 326 U.S. 249, 256 (1945)). In *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401 (2015), the Supreme Court reaffirmed *Brulotte*. The Supreme Court stated that "[a]llowing even a single company to restrict its use of an expired or invalid patent…would deprive the consuming public of the advantage to be derived from free exploitation of the discovery. And to permit such a result, whether or not authorized by express contract, would impermissibly undermine the patent laws." *Kimble*, 135 S. Ct. at 2407 (alteration in original) (citations and internal quotation marks omitted).

Here, it is undisputed that Defendants entered into the Challenged Agreements with multiple generic drug companies that had asserted non-infringement defenses and were

challenging the validity of the '703 patent (which purportedly protected Namenda IR). And it is also undisputed that, pursuant to the Pediatric Extension Provision in the Challenged Agreements, the 7 Generic Companies agreed not to come to market with their generic versions of Namenda IR until July 11, 2015 – *three months' after the expiration of the '703 patent* on April 11, 2015. SMF ¶¶ 26 (Amneal), 40 (Dr. Reddy's), 54 (Lupin), 68 (Mylan), 82 (Orchid), 95 (Sun), 109 (Teva). This is prohibited by *Brulotte*.[19]

Accordingly, the Challenged Agreements, each of which contained the Pediatric Extension Provision that preserved Defendants' patent monopoly beyond the scope of the '703 patent, constitute impermissible "reservations" of Defendants' patent monopoly by which Defendants could engage in market allocation and price-fixing, and therefore amount to naked restraints in violation of Section 1 of the Sherman Act. *See, e.g.*, *Palmer*, 498 U.S. at 48-50; *Topco Assocs.*, 405 U.S. at 600-601 ("*Topco*"); *Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205, 225 (2d Cir. 2004) ("Horizontal agreements among competing sellers to fix prices or restrict output are, absent more, *per se* violations of Section 1 of the Sherman Act.") (citations omitted); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003) ("[P]rice fixing and market division, are considered unreasonable *per se*[.]") (citations omitted).

The Supreme Court's *Topco* decision is instructive in this regard. Writing for the *Topco* court, Justice Marshall began by outlining that "Section 1 of the Sherman Act provides, in relevant part, [that] '[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal . . . .'" *Id.* at 600-601 (quoting Section 1 of the Sherman Act). Justice

[19] The Department of Justice has supported the Plaintiffs' analysis in this regard. *See* note 5, *supra*.

Marshall then contrasted the "rule of reason" with *per se* rules, and explained the rationale for the latter, as he wrote:

> While the Court has utilized the 'rule of reason' in evaluating the legality of most restraints alleged to be violative of the Sherman Act, it has also developed the doctrine that certain business relationships are *per se* violations of the Act without regard to a consideration of their reasonableness. In *Northern Pacific R. Co. v. United States*, 356 U. S. 1, 5 (1958), Mr. Justice Black explained the appropriateness of, and the need for, *per se* rules:
>
> > '[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use. This principle of *per se* unreasonableness not only makes the type of restraints which are proscribed by the Sherman Act more certain to the benefit of everyone concerned, but it also avoids the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable—an inquiry so often wholly fruitless when undertaken.'

Topco, 405 U.S. at 607. Justice Marshall then turned his attention to discussing the specifics of naked restraints of trade:

> One of the classic examples of a *per se* violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition. Such concerted action is usually termed a 'horizontal' restraint . . . . This Court has reiterated time and time again that '[h]orizontal territorial limitations . . . are naked restraints of trade with no purpose except stifling of competition.'

Topco, 405 U.S. at 608 (citations omitted). Justice Marshall then explained the reasons why naked restraints of trade were to be rejected, and emphasized the importance of the Sherman Act, as he stated:

> In applying these rigid rules, the Court has consistently rejected the notion that naked restraints of trade are to be tolerated because they are well intended or because they are allegedly developed to increase competition . . .

> Antitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms.

Id. at 610 (citations omitted).

It is significant to note that the Pediatric Extension Provision is exactly the kind of restraint contained in a licensing arrangement that the U.S. Department of Justice and Federal Trade Commission recently announced they would challenge under the *per se* rule. U.S. Dep't. of Justice, et al., *Antitrust Guidelines for the Licensing of Intellectual Property*, at 17 (Jan. 12, 2017) (available at https://www.justice.gov/atr/IPguidelines/download). Generally, these two agencies will challenge a given restraint under the *per se* rule if (1) there is no efficiency-enhancing integration of economic activity and (2) the restraint itself is one that has been accorded *per se* treatment. Specifically, the agencies stated:

> To determine whether a particular restraint in a licensing arrangement is given per se or rule of reason treatment, the Agencies will assess whether the restraint in question can be expected to contribute to an efficiency-enhancing integration of economic activity. In general, licensing arrangements promote such integration because they facilitate the combination of the licensor's intellectual property with complementary factors of production owned by the licensee. A restraint in a licensing arrangement may further such integration by, for example, aligning the incentives of the licensor and the licensees to promote the development and marketing of the licensing technology, or by substantially reducing transactions costs. If there is no efficiency-enhancing integration of economic activity and if the type of restraint is one that has been accorded per se treatment, the Agencies will challenge the restraint under the per se rule.

Id.

Here, it is clear that the Pediatric Extension Provision does not create any "efficiency-enhancing integration" between Defendants and the 7 Generic Companies. Indeed, the Pediatric Extension Provision does not create a situation in which the Defendants and the 7 Generic Companies were, for example, co-mingling their formulations, manufacturing processes, sales or

marketing efforts, or any other type of behavior. Moreover, the Pediatric Extension Provision did not create any other different type of "efficiency" because the 7 Generic Companies separately obtained FDA final approval before the '703 patent expired (and thus pediatric exclusivity could not bar their market entry upon the expiration of the '703 patent). And, of course, as discussed above, the Pediatric Extension Provision was a mechanism by which Defendants engaged in market allocation and price-fixing – restraints that have been accorded *per se* treatment.

The inclusion of the Pediatric Extension Provision in the Challenged Agreements improperly preserved Defendants' patent monopoly beyond the scope of the '703 patent. This created the opportunity for Defendants to allocate the market and fix prices. Because it is undisputed that the Challenged Agreements restricted competition for a period of time during which none of the 7 Generic Companies was precluded in any way, or for any reason, from selling its generic version of Namenda IR, this Court should rule, based on the reasoning inherent in *Topco*, that the Pediatric Extension Provision in the Challenged Agreements is an unlawful naked restraint of trade that is a *per se* violation of the Sherman Act.

B. Pediatric Exclusivity Neither Extended the Patent Term Nor Prevented the 7 Generic Companies From Obtaining FDA Final Approval for their ANDAs.

At the motion to dismiss stage of this case, Defendants argued that Plaintiffs could not allege that Defendants delayed generic entry beyond the expiration of the '703 patent because Defendants' pediatric exclusivity, obtained from the FDA on June 18, 2014 (*years after* the execution of the Challenged Agreements), extended the '703 patent term by six months (to October 11, 2015) and that, therefore, the 7 Generic Companies' agreement not to come to market with their generic versions of Namenda IR until July 11, 2015 actually permitted the 7

Generic Companies to launch their generic Namenda IR three months *prior* to the end of the "extended" patent term. Defendants' Motion to Dismiss Br. at 53-54.

But Defendants' claim that their receipt of patent exclusivity extended the term of the '703 patent is wrong. The law on this matter is clear: Pediatric exclusivity does not extend a patent term. Indeed, "[t]he pediatric exclusivity period is not an extension of the term of the patent." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1343 (Fed. Cir. 2015) (holding that a manufacturer may not sue for patent infringement or recover Patent Act damages based on "sales during the post-expiration period of pediatric exclusivity"). Rather, pediatric exclusivity "'extends the period during which approval of an abbreviated new drug application (ANDA)…may not be made effective by the FDA.'" *Altana Pharma AG v. Teva Pharm. USA, Inc*., No. 04-2355, 2012 WL 2068611, at *2 (D.N.J. June 7, 2012) (*quoting* U.S. F.D.A., Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food Drug and Cosmetic Act, (Sept. 1999), (available at http://www.fda.gov/OHRMS /DOCKETS/98fr/980265gd.pdf)).

Pediatric exclusivity is a regulatory exclusivity and the Defendants do not dispute this. *See* Defendants' Motion to Dismiss Br. at 14 ("In addition to patent exclusivity, a pharmaceutical innovator is eligible for Congressionally-conferred periods of *regulatory exclusivity*—such as *pediatric exclusivity*…"). (emphasis added). Defendants' reliance on their pediatric exclusivity is nothing more than a pretext to cover up their illegal agreements with the 7 Generic Companies that ensured that there would be no generic competition until after the expiration of the '703 patent term.

In support of their dubious patent extension argument, Defendants have maintained that the FDA could not grant final approval to any generic until after the pediatric exclusivity period

had expired. *See* Defs.' Br. at 50-52. But this contention is without merit. Here, consistent with the statute, the FDA did in fact grant final approval to the 7 Generic Companies before the start of the pediatric exclusivity period, and never sought to rescind that approval.[20] Defendants' pediatric exclusivity alone would never prevent FDA final approval for the first-filing generic drug companies that filed and maintained Paragraph IV certifications[21] before the '703 patent expired.

When a generic company files a Paragraph IV certification, the FDA will forebear in granting final approval before the expiration of the applicable patent only if a court hearing the infringement litigation "determines that the patent is valid and would be infringed." 21 USC § 355a(c)(1)(B)(II) ("[I]f the drug is the subject of a listed patent for which [a Paragraph IV certification has been submitted], and in the patent infringement litigation resulting from the certification *the court determines that the patent is valid and would be infringed, the period during which an application may not be approved*…shall be extended by a period of six months

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[20] Here, the FDA granted final approval to the ANDAs of the 7 Generic Companies before Defendants' pediatric exclusivity began on April 11, 2015. SMF ¶¶ 28 (Amneal), 42 (Dr. Reddy's), 56 (Lupin), 76 (Mylan), 84 (Orchid), 97 (Sun), 111 (Teva).

[21] To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification a 180-day period to market the generic version of the drug, during which time the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA, and certifies that the unexpired patents listed in the Orange Book as covering the brand product are either invalid or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first-filing generic has been on the market for 180 days, or until the first-filer exclusivity has been forfeited. The 180-day exclusivity may be shared by multiple first-filers. Under the "shared exclusivity" approach, any one of the first-filers may commence the 180-day generic exclusivity by commercially marketing the drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I) (Later-filing ANDAs "shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug…by *any* first applicant."). (emphasis added).

after the date the patent expires (including any patent extensions).") (emphasis added).

Not only did Defendants never obtain such a court determination, they prevented a court from ever being able to make any determination of the sort by orchestrating the execution of the Challenged Agreements. Indeed, Defendants' own conduct – their settlement with multiple generic companies during the infringement actions, up to five years prior to the expiration of the '703 patent – removed any possibility that a court would determine that the '703 patent was valid and would be infringed.

In so settling, Defendants gave themselves something they never could have had without a victory in the patent case: A lack of competition from the 7 Generic Companies *after* patent expiry. This protection from competition post-patent expiry was a *per se* unlawful market division. *See, e.g., Palmer*, 498 U.S. at 48-50; *Topco*, 405 U.S. at 600-601, 607-610. Indeed, "[h]orizontal agreements among competing sellers to fix prices or restrict output are, absent more, *per se* violations of Section 1 of the Sherman Act." *Freedom Holdings*, 357 F.3d 205 at 225.

Furthermore, Defendants' argument that the FDA could not grant final approval to any generic companies until after their pediatric exclusivity period had expired completely ignores the facts as they actually occurred. Defendants' pediatric exclusivity never served as a bar that prevented the 7 Generic Companies from obtaining FDA final approval and coming to market with their generic versions of Namenda IR. Indeed, the 7 Generic Companies that had filed and maintained Paragraph IV certifications prior to the '703 patent's expiration all received final approval from the FDA even though Defendants obtained pediatric exclusivity. And, in fact, at least four of the Generic Companies – Dr. Reddy's, Sun, Teva and Orchid – had already received

final approval for their ANDAs years before Defendants obtained pediatric exclusivity in June 2014.

Because they had received FDA final approval, the 7 Generic Companies were, therefore, free to launch their generic versions of Namenda IR at any time, irrespective of any supposedly available pediatric exclusivity, but-for their entering into the Challenged Agreements with Defendants. *See* FDA, Draft Guidance for Industry – 180-Day Exclusivity: Questions and Answers (Jan. 2017) answering Question 20 at 13-14, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM536725.pdf ("[T]he first [to file applicants] approved prior to the start of pediatric exclusivity [*e.g.*, the 7 Generic Companies] do[] not need to change [their Paragraph IV certifications] upon patent expiry and pediatric exclusivity does not affect the approval of the first applicant[s'] ANDA."); *see also Ranbaxy Labs., Ltd. v. Burwell*, 82 F. Supp. 3d 159, 169 (D.D.C. 2015) ("Once an ANDA has been granted final approval, the manufacturer may begin selling the drug in interstate commerce. *See* 21 U.S.C. § 355(a)."); FDA's Drugs@FDA Glossary, available at http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=glossary.page (definition of "Approval Letter" states that "[a final] approval letter is an official communication from FDA to a drug application…sponsor that allows the commercial marketing of the product").

When the dust settles, Defendants will never be able to explain how the FDA granted final approval to the 7 Generic Companies and never revoked those approvals, even during the period when pediatric exclusivity ran. Defendants' pediatric exclusivity alone could have never prevented or delayed the 7 Generic Companies from coming to market with their generic versions of Namenda IR.

IV. CONCLUSION

For the reasons stated above, this Court should grant partial summary judgment that establishes that the Pediatric Extension Provision in the Challenged Agreements is a naked restraint of trade that constitutes a *per se* violation of the Sherman Act.

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Respectfully Submitted:

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CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2017, I electronically filed the above memorandum by CM/ECF system.

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